

Rejection of Claims 50-59 and 69 Under 35 U.S.C. Section 112, First Paragraph

Claims 50-59 and 69 are rejected under 35 U.S.C. Section 112, first paragraph as not being enabled by the specification. According to the Examiner, the evidence in the specification is conflictory, specifically, it does not predictably teach an association of a polynucleotide to which SEQ ID NO:1 hybridizes with breast cancer. Furthermore, the Examiner states that the specification does not provide any guidance with regard to the presence or absence of a genomic DNA sequence that hybridizes with SEQ ID NOS 1-5 and breast cancer. The Examiner states that "[T]he sequence appears to be present and expressed in normal tissue, but no conclusions can be made as to its presence in the genome of other tissues because no teachings have been provided in the specification."

Claims 50-59 and 69 have been deleted and replaced with new claims 70-79. In view of the deletion of these claims, Applicants submit that this rejection is now moot and should be withdrawn.

Rejection of Claims 50-69 Under 35 U.S.C. Section 101

Claims 50-69 are rejected under 35 U.S.C. Section 101 as lacking a specific and substantial asserted utility or well-established utility. According to the Examiner, the specification does not disclose a correlation between the recited polynucleotides and the existence of breast cancer such that the skilled artisan would be able to have a real word context for the use of the claimed method. Claims 50-59 and 69 have been deleted. New claims 70-79 have been added. Applicants will now address this rejection with respect to claims 60-68 and new claims 70-79.

Applicants submit that the claimed invention possesses a specific and substantial utility. Specifically, BS106 is a previously unknown polynucleotide that encodes for a protein that is useful as a diagnostic marker for breast cancer in a patient. The attached 37 C.F.R. Section 1.132 declaration of Paula N. Friedman demonstrates the importance and usefulness of this marker. In her Declaration, Dr. Friedman describes the results of

an RT-PCR assay on lymph node tissue from breast cancer and non-breast cancer patients. The results of this assay conclusively demonstrate BS106 gene is expressed in breast cancer cells that have escaped the primary tumor and establish that BS106 can be used as a marker to detect breast cancer.

Thus, the above scientific facts support the utility of BS106 and illustrate that BS106 can be used to detect breast cancer. Therefore, Applicants submit that this rejection should be withdrawn.

Rejection of Claims 67-68 Under 35 U.S.C. Section 112, First Paragraph

Claims 67-68 are rejected under 35 U.S.C. Section 112, first paragraph. Claims 67-68 have been amended to address the Examiner's rejection. In view of these amendments, Applicants submit that this rejection should be withdrawn.

Rejection of Claims 68 and 69 Under 35 U.S.C. Section 112, First Paragraph

Claims 68-69 are rejected under 35 U.S.C. Section 112, first paragraph. Claim 68 has been amended to remove the reference to "a gene". Claim 69 has been deleted. In view of the amendment to claim 68, Applicants submit that this rejection should be withdrawn.

Rejection of Claim 67 Under 35 U.S.C. Section 112, Second Paragraph

Claim 67 is rejected under 35 U.S.C. Section 112, second paragraph as being indefinite. Applicants have amended claim 67 to refer to an amino acid sequence.

Applicants submit that the claims 60-68 and 70-79 are in condition for allowance.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If any

additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 01-0025.



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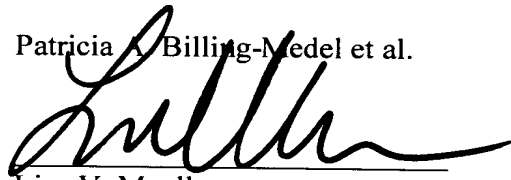
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MARKED UP VERSION SHOWING CHANGES MADE:

Please amend claims 67 and 68 as follows:

67. (Amended). An [gene comprising a] isolated and purified amino acid
[nucleic acid sequence selected from the group consisting of] comprising SEQ ID NO:16
[and degenerate codon equivalents thereof] and fragments thereof.

68. (Amended). An (gene comprising a] isolated and purified nucleic acid
sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and
degenerate codon equivalents thereof.